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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,808	08/17/2000	Marlene Belfort	454311-2201.1	6356

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

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DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/641,808

Applicant(s)

Belfort et al

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-72 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-33, drawn to inteins, classified in class 530, subclass 350.
  - II. Claims 34-38 and 67-72, drawn to DNA, classified in class 536, subclass 23.1.
  - III. Claims 39-47, drawn to methods of producing a protein enzymatically, classified in class 435, subclass 68.1.
  - IV. Claims 48-49, drawn to methods of purification, classified in class 435, subclass 7.1.
  - V. Claims 50-52, drawn to methods of preparing an intein comprising random mutagenesis, classified in class 435, subclass 69.1.
  - VI. Claims 53-60, drawn to methods of screening for intein cleavage activity, classified in class 435, subclass 7.4.
  - VII. Claims 61-66, drawn to methods of determining amino acid residues in an intein that play a role in cleavage activity, classified in class 435, subclass 4.
2. The inventions are distinct, each from the other because of the following reasons:

Invention I drawn to a polypeptide and Invention II drawn to a polynucleotide are distinct since they are products with different structure and biological properties. The polypeptide is made of amino acids whereas the claimed nucleic acid is made of nucleotides. Further methods

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known in the art used to make the polypeptide require different reagents and parameters from the methods of making DNA encoding the protein and the method of making the polypeptide does not require the DNA. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography.

Invention III, drawn to methods of producing a protein enzymatically, is distinct from Groups I-II and IV-VII, since it requires additional biological reagents and parameters for producing the protein.

Invention IV, drawn to methods of purifying a protein, is distinct from Groups I-III and V-VII, since it requires additional biological reagents and parameters for purifying the protein.

Invention V, drawn to methods of preparing an intein comprising random mutagenesis, is distinct from Groups I-IV and VI-VII, since it requires additional biological reagents and parameters for inserting nucleotide substitutions.

Invention VI, drawn to methods of screening for intein cleavage activity, is distinct from Groups I-V and VII, since it requires additional biological reagents and parameters detecting intein cleavage activity.

Invention VII, drawn to methods of determining amino acid residues in an intein that play a role in cleavage activity, is distinct from Groups I-VII, since it requires additional biological reagents and parameters for detecting amino acids which are responsible for biological activity.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225.

Mark Navarro

Primary Examiner

February 13, 2003